

REMARKS

Claim status:

With entry of the instant amendment claims 1 – 30 are pending. Claims 1, 3 and 25 have been amended. Claims 26 – 30 are new. Applicants submit new matter has not been introduced by the present amendment.

Independent claims 1 and 25 have been amended to correct minor grammatical mistakes and further to define the abbreviation “HCIC” as Hydrophobic Charge Induction Chromatograph. In addition, the clause “wherein said pH gradient is incrementally decreased and the immunoglobulin is substantially free of other proteins” has been included in claim 25.

New claims 26 – 30 depend from independent claim 25. Claims 26 and 27 further define the elution step with respect to the pH gradient and support is found at page 14, paragraph [69] and page 19, example 3 of the disclosure. Claims 28 - 30 further define the immunoglobulin and support is found in the original claims and in the examples.

Applicants acknowledge the Examiner’s allowance of claims 1, 2, 4, 6 – 13 and 15 – 19 and further the statement that claim 3 would be allowable if rewritten or amended to overcome the 35 U.S.C. 112, 2nd paragraph rejection.

Priority:

As indicated in the first paragraph of the specification and in the executed declaration, Applicants’ claim to priority is based on provisional application 60/411,537.

The first paragraph of the specification recites that the instant application is related to various co-pending provisional applications. These applications are Attorney Docket Number GC741P having USSN 60/373,889, filed April 18, 2002 and Attorney Docket Number GC776P having USSN 60/411,540, filed Sept. 10, 2002. US Patent Publication 2004/0018573, which published Jan. 29, 2004 and was filed on April 17, 2003 (USSN 418,836 having Attorney Docket Number GC741-2), claims priority to the two cited provisional applications (GC741P, USSN 60/373,889 and GC776P, USSN 60/411,540).

Objection to the Drawings:

Applicants are concurrently filing with this amendment a set of formal drawings, which do not include color photographs.

Objection to the Disclosure:

The disclosure has been amended to delete browser-executable code. The address for the ATCC has been provided as opposed to the code for the web site.

Additionally, the Examiner has stated that proper antecedent basis for the claimed subject matter, and specifically the pH ranges cited in claims 14 and 15 and the steps range recited in claim 17, are not recited in the specification. While Applicants acknowledge that exact language as recited in the claims may not be recited in other parts of the specification, the Examiner is reminded that the original claims are self-supporting and considered part of the specification.

Rejection Under 35 U.S.C. §112, 2nd paragraph:

The amendment to claim 3 renders moot the rejection under the second paragraph of section 112.

Rejection under 35 U.S.C. §119(e):

The Examiner has stated that claims 1 – 4, 6 – 13, 16, 18 and 19 are deemed to be entitled to the benefit of the filing date of provisional application 60/411,537 but that claims 5, 14, 15, 17 and 20 – 25 are not deemed to be entitled to the benefit of the filing date of the provisional application.

Applicants contend that claims 14 and 15 are supported by the provisional application. At page 13, paragraph [63] of the provisional patent disclosure, the elution buffers are disclosed as

- (a) #1, pH 5.6;
- (b) #2, pH 4.75;
- (c) #3, pH 4.00; and
- (d) #4, pH 2.5.

Additionally at page 15 of the provisional application under “Materials” the disclosure teaches the same elution buffers and further that the loading buffer had a pH of 8.2. Additionally

with respect to claim 17, the provisional application discloses a step pH gradient comprising four steps.

Rejections under 35 USC §102(e) and 35 USC §103(a):

The Examiner has rejected claims 5, 14, 20 – 22 and 25 as being anticipated by Power et al (US Pat, Pub. 2004/0018573). The published application discloses an embodiment of the instantly claimed purification method (See example 14). However, the corresponding provisional application does not include such disclosure. Applicants' provisional application, which corresponds to the instant application, was filed before the filing date and publication date of the Power et al. conversion application.

In addition, the Examiner has rejected claims 23 and 24 as being obvious over Power et al as applied to claims 5, 14, 20 – 22 and 25 and further in view of Burton et al., (USP 5,652,348). Power et al., US Pat. Pub 2004/0018573 is recited in the first paragraph of Applicants' disclosure as discussed herein above. While the present application and the Power et al. application have different inventors, both applications were commonly owned at the time of the current invention and said inventors were under an obligation to assign the inventions to Genencor International Inc.

The Examiner has cited Burton as the patent covering HCIC in a radial flow column or expanded bed column as claimed in claims 23 and 24. While Burton may teach radial flow and expanded bed columns – Applicants are claiming an advance in HCIC separation technology - that is exposure to a pH gradient in an incremental step-wise manner for separation of a protein from other proteins and specifically fusion analogs.

Rejection under 35 USC §102(b):

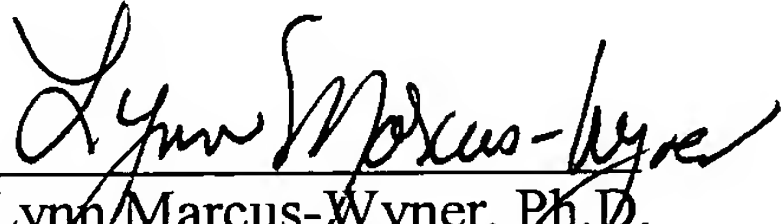
The Examiner has rejected claim 25 as being anticipated by Guerrier et al. Claim 25 has been amended to include the recitation that the eluting step is accomplished by exposure to a pH gradient which is incrementally decreased. Guerrier *et al.* does teach isolation and purification of antibodies using HCIC that is achieved by incrementally lowering the pH. In the Guerrier examples, the loading or starting buffer pH is typically pH 8.0 (although other pH values are used) and the antibodies are desorbed using elution buffer at pH 4.0. Various other pH values are taught, but the examples are directed to a loading buffer pH and one elution buffer pH. Significantly, there is no

teaching of exposure to elution buffers by decreasing the buffer pH over a pH gradient in an incremental manner, and more specifically there is no teaching that the step-wise exposure should include a loading buffer of about pH 8.2 and then four additional elution buffer exposures at about pH 5.6; pH 4.75; pH 4.00; and finally pH 2.5. Applicants submit that the amendment renders this present rejection moot.

Applicants respectfully submit that the pending claims are in condition for allowance. Allowance of the application is kindly requested. If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 846-7620.

Respectfully submitted,

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